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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/469,717	12/21/1999	HUGH L. MARCISO JR.	353532000710	5304

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3762	

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17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/469,717	Applicant(s) NARCISO, HUGH L.
	Examiner Kristen L Drolesch	Art Unit 3762
<i>-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --</i> Period for Reply		
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.		
<ul style="list-style-type: none"> - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). 		
Status		
1) <input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>13 May 2003</u> . 2a) <input type="checkbox"/> This action is FINAL. 2b) <input checked="" type="checkbox"/> This action is non-final. 3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.		
Disposition of Claims		
4) <input checked="" type="checkbox"/> Claim(s) <u>47-60 and 63</u> is/are pending in the application. 4a) Of the above claim(s) _____ is/are withdrawn from consideration. 5) <input type="checkbox"/> Claim(s) _____ is/are allowed. 6) <input checked="" type="checkbox"/> Claim(s) <u>47-60 and 63</u> is/are rejected. 7) <input type="checkbox"/> Claim(s) _____ is/are objected to. 8) <input type="checkbox"/> Claim(s) _____ are subject to restriction and/or election requirement.		
Application Papers		
9) <input type="checkbox"/> The specification is objected to by the Examiner. 10) <input checked="" type="checkbox"/> The drawing(s) filed on <u>21 December 1999</u> is/are: a) <input checked="" type="checkbox"/> accepted or b) <input type="checkbox"/> objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). 11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action. 12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner.		
Priority under 35 U.S.C. §§ 119 and 120		
13) <input type="checkbox"/> Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) <input type="checkbox"/> All b) <input type="checkbox"/> Some * c) <input type="checkbox"/> None of: 1. <input type="checkbox"/> Certified copies of the priority documents have been received. 2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____. 3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.		
14) <input type="checkbox"/> Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). a) <input type="checkbox"/> The translation of the foreign language provisional application has been received. 15) <input checked="" type="checkbox"/> Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.		
Attachment(s)		
1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 6) <input type="checkbox"/> Other:		

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/13/03 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 47-60, and 63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 60, applicants set forth a tubular member formed of deformable material that is transformable upon the application of energy from a fluent state to a non-fluent state, in other words from a liquid to a solid. However, beginning on page 3, line 30 of the specification, "deformable" is defined as a material transformable from a solid to a moldable fluent state upon the application of energy. In addition, the specification beginning on page 4, line 12 describes "curable" materials as those that are transformed from a liquid to a solid state by the application of energy. Therefore, the inclusion of the word "deformable" in the claim is not consistent with the functional language that describes a "curable" material.

Furthermore, if applicant intends to claim a "curable" material, the specification does not provide support for a tubular member formed of a curable material. In contrast, the specification

states on page 4, lines 16, that the curable material is preferably applied to a tissue surface as a liquid or viscous gel. Further support for the curable material being a liquid or viscous gel rather than a tubular member is found on pages 14, line 24 - page 17, line 2.

Regarding claims 47-48, it is unclear how the fluent material can be pre-shaped and have a bend, or extend at 30-45⁰ to a longitudinal centerline.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 49-55, and 58-60, are rejected under 35 U.S.C. 102(e) as being anticipated by Slepian (5,634,946). The examiner has interpreted the claims to cover a curable material, rather than a deformable tube. Slepian shows a fastener comprising a coating of curable material, which is transformable upon application of energy between a fluent state and a non- fluent state (Col. 11, lines 36-48).

6. With respect to claims 49-51, Slepian shows that the material is formed of a biocompatible, bioerodable polymeric material (Col. 7, lines 32-44, Col. 8, lines 4-15).

Regarding claim 52, Slepian shows the polymer is either a homopolymer or a copolymer (Col. 7, lines 46-49, Col. 11, lines 36-39).

With respect o claim 53, Slepian shows the polymeric material is polycaprolactone (Col. 8, lines 16-46).

Regarding claims 54-55, Slepian shows the material has an adhesive surface (Col. 12, lines 9-12, Col. 12, lines 52-56, Col. 14, lines 40-46)

With respect to claims 58-59, Slepian shows the material is impregnated with anti-platelet, anti-thrombus, anti-inflammatory, and anti-proliferative compounds (Col. 9, lines 25-43).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 56-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slepian in view of Pathak (5,662,712). Slepian is as explained before. Although Slepian does not teach including in the tubular member a chromophore or dye, attention is directed to Pathak which teaches forming polymeric materials that include a chromophore such as a dye or pigment (Col. 2, lines 54-59). Pathak teaches that the chromophore serves to absorb light produced by a light source and convert it to thermal energy that acts to heat the polymer. It would have been obvious to one with ordinary skill in the art at the time the invention was made to include in the tubular member of Slepian a chromophore in the form of a dye, as taught by Pathak in order for the tubular member to be transformable by the application of light energy.

9. Claim 63 is rejected under 35 U.S.C. 103(a) as being unpatentable over Slepian in view of Hubbell (5,410,016). Slepian is as explained before. Although Slepian does not teach that the material is selected from a group consisting of polyethylene-glycol (PEG) base hydrogels,

acrylates, and acrylated urethanes, attention is directed to Hubbell which teaches tissue contacting materials formed from of polyethylene-glycol (PEG) base hydrogels, acrylates, and acrylated urethanes (Col. 5, lines 15-23, and Col. 27, lines 53-55). Hubbell teaches that the acrylates permit rapid polymerization and gelation and can be polymerized by several initiating systems. Hubbell teaches that PEG is hydrophilic and water soluble and has excellent biocompatibility. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to use this group of materials for the device of Slepian since Hubbell teaches that this group of materials are rapidly transformable upon the application of energy between a non-fluent state and a fluent state, are water soluble, and have excellent biocompatibility.

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claim 60 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 46 of U.S. Patent No. 6,110,188, in view of Slepian (5,634,946). Although U.S. Patent No. 6,110,188 fails to claim the material is transformable upon the application of energy between a fluent state and a non-fluent state, attention is directed

to Slepian which teaches the application of a deformable tube to a vessel lumen which is transformable from a non-fluent state to a fluent state can alternatively be accomplished by the application of a curable coating (transformable from a fluent to non-fluent state) (Col. 11, lines 36-48). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to employ the curable coating of Slepian for the deformable tube transformable from a non-fluent state to a fluent state of Claim 46, wherein so doing would amount to mere substitution of one functional equivalent for another that would work equally well on the device of claim 46.

Response to Arguments

12. Applicant's arguments with respect to claims 47-60 and 63 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen L Drolesch whose telephone number is 703-605-1185. The examiner can normally be reached on M-F, 8:00 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angie Sykes can be reached on 703-308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



kld
June 13, 2003



KENNEDY SCHAETZLE
PRIMARY EXAMINER
6-15-03